

Diagnostic Products Corporation  
5700 West 96th Street  
Los Angeles, CA 90045  
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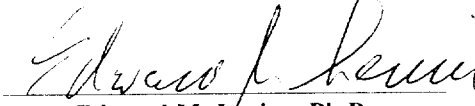


### 510 (k) Summary Safety and Effectiveness

*This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.*

**Name:** Diagnostic Products Corporation  
**Address:** 5700 West 96th Street  
Los Angeles, California 90045-5597  
**Telephone Number:** (213) 776-0180  
**Facsimile Number:** (213) 776-0204  
**Contact Person:** Edward M. Levine, Ph.D.  
Director of Clinical Affairs  
**Date of Preparation:** July 26, 1996  
**Device Name:** PSA Control Module  
**Trade:** Device intended as an aid in monitoring the performance  
of DPC's Coat-A-Count® PSA IRMA assay and the  
IMMULITE PSA assay.  
**Catalog Number:** PSACM  
**Classification:** Class I device, 82-JJX (21 CFR 862.1660)  
**Manufacturer:** Diagnostic Products Corporation  
5700 West 96th Street  
Los Angeles, California 90045-5597  
**Establishment Registration Number:** DPC's Registration Number is 2017183  
**Description of Device:** DPC's PSA Control Module is an assayed tri-level  
control intended for use in the quality control of DPC's  
Coat-A-Count PSA IRMA assay and DPC's IMMULITE  
PSA assay.  
**Intended Use of the Device:** DPC's PSA Control Module is designed for use as  
an assayed quality control serum in the clinical chemistry  
laboratory to monitor the accuracy and precision of both  
the Coat-A-Count PSA IRMA and IMMULITE PSA  
procedures. They are intended strictly for in vitro  
diagnostic use  
**Clinical Studies:** Not applicable  
**Conclusion:**

The conclusions drawn from the nonclinical tests demonstrate that the device is safe and effective.

  
Edward M. Levine, Ph.D.  
Director of Clinical Affairs

  
Date